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EXAMINER

THANH, LOAN H

ART UNIT PAPER NUMBER

3763

DATE MAILED: 03/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/726,841

Applicant(s)

FLEEMAN, BRIAN J.

Examiner

LoAn H. Thanh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 4,5,7-12 and 15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4,5,7-11 and 15 is/are rejected.
- 7) ☒ Claim(s) 12 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6,9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Response to Amendment***

The objections to the specification and the claim have been obviated in view of the amendment filed 12/27/02.

The claim rejection under 35 USC §112, 2<sup>nd</sup> paragraph has been obviated in view of the amendment filed 12/27/02.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4-5, 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Piontek et al. (U.S. Patent No. 5,071,405).

Piontek et al. disclose a patient feeding tube (10) comprising an elongated tube (12) having a distal end and a proximal portion and a fixture operably coupled to the proximal portion. Piontek et al. teach an intermediate coupling member considered to be the y-port (22). See figure 1. The intended use of a device imposes no limitation to the claim in the absence of distinguishing structural features. With respect to the claimed functional limitations, Piontek et al. is functionally adaptable to permit attachment to a CO<sub>2</sub> detecting machine. Applicant's language of "adapted to permit attachment" and

"may be detected" is considered to have no additional structure. Piontek et al. is capable of performing the functions.

With respect to claim 11, a fixture is located at the proximal portion of a feeding tube (12) and the fixture having first and second tubular legs (20, 22), said first leg (20) having a connection end at element 17 and a second leg in communication with the first leg, and an intermediate coupling member considered to be the other end of the first leg which is adapted for connection with a CO<sub>2</sub> detecting machine.

Claims 4,15 are rejected under 35 U.S.C. 102(b) as being anticipated by Clegg et al. (U.S. Patent No. 5,057,093)

Clegg et al. show an elongated tube (66), fixture (34), which is removably secured to the intermediate coupling member (30). See col. 7, lines 5-10 and figs. 3,6,8.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Piontek et al. ( U.S. Patent No. 5,071,405) in view of Kimball et al. (U.S. Patent No. 6,258,046).

Piontek et al. teach all the limitations of the claims except for a CO<sub>2</sub> detecting machine. Kimball et al. teach a CO<sub>2</sub> machine (30 ) for detecting the CO<sub>2</sub> (via the

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sensor) in the analogous art of tubes placed in the digestive systems. Kimball et al. teach CO<sub>2</sub> (PCO<sub>2</sub>) to be detected, monitored and measured for assessing perfusion failure in the stomach and intestines. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the feeding device of Piontek et al. with a CO<sub>2</sub> machine as taught by Kimball et al. in order to assess the perfusion failure in the tissues of the digestive tract of the patient.

#### ***Allowable Subject Matter***

Claim 12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Response to Arguments***

Applicant's arguments with respect to claims 4-5, 7-11 have been considered but are not persuasive.

With respect to applicant's arguments on page 5, 2<sup>nd</sup> paragraph filed 12/27/01, the Examiner is not in agreement with applicant. Piontek et al. does disclose the elements of the fixture and at least one intermediate coupling member as shown above. Further, it appears that applicant is arguing intended use with respect to the remarks Piontek et al. would not be adapted for connection to a CO<sub>2</sub> detecting machine. Lacking any further distinguishing structural features, the Examiner is maintaining that Piontek et al. is capable of performing the function. Further the CO<sub>2</sub> detecting machine

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is not positively claimed in independent claims 4, 11. Applicant is suggested to add more structure to distinguish from the prior art.

With respect to applicant's arguments regarding the 103 rejection on page 5-6, Kimball is prior art as a 102(e). Kimball et al. teach a CO2 sensor at the distal end of the tube which is connected to the CO2, detecting machine at the proximal end of the tube. Kimball et al. happens to convert the CO2, measurement as a representative of blood flow. In other words, blood flow is representative of the CO2 that is detected by the CO2 detecting machine (30). See col. 3 of Kimball et al. lines 10-15, 47-53.

### ***Conclusion***


Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (703) 305-0038. The examiner can normally be reached on Monday to alternating Fridays (7:00 am-4:30 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



LoAn H. Thanh  
Examiner  
Art Unit 3763

LT  
March 9, 2003